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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,845	01/26/2006	Jadwiga Bienkowska	ARS-113	2205

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	**PAPER NUMBER**
1649	
MAIL DATE	**DELIVERY MODE**
03/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,845	BIENKOWSKA ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 42 and 48-50 are objected to as reciting an improper Markush Group.

MPEP 803.02 states:

"Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."

Applicant is advised that claims 42 and 48-50 are each improper Markush claims because the plurality of polypeptide, nucleic acid, compounds, ligands and products recited in these claims are structurally and functionally distinct and lack a common utility based upon a shared structural feature that is lacking from the prior art.

Each of these proteins, nucleic acids, mimetic, compounds, ligands, host cells and transgenic animals as recited in claims are independent and distinct chemical compounds and products lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art proteins or nucleic acids. Methods of using protein compositions are materially and methodologically distinct from the same methods performed with nucleic acid molecules. Furthermore, the PCT rules provide for the examination of the first claimed product, the first claimed method of making that product, and the first claimed method of

using that product in one application, but do not provide for the examination of multiple products or unrelated methods. For example, the protein product and the nucleic acid product differ in structure, biological function, and capable uses. The plurality of methods recited in claims 48-49 each use different steps and/or different reagents corresponding to the distinct technical features, and exhibit different effects, functions and outcomes.

2. Accordingly, the following Groups I- XV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted:

I. Claims 42-47, in so far as they are drawn to a composition of matter encompassed by the amino acid sequence of SEQ ID NO: 2.

II. Claims 42-47, in so far as they are drawn to a composition of matter encompassed by the amino acid sequence of SEQ ID NO: 4.

III. Claims 42-47, in so far as they are drawn to a composition of matter encompassed by the nucleic acid sequence of SEQ ID NO: 1.

IV. Claims 42-47, in so far as they are drawn to a composition of matter encompassed by a transgenic animal.

V. Claims 42-47, in so far as they are drawn to a composition of matter encompassed by ligands that bind polypeptides.

VI. Claims 42-47, in so far as they are drawn to a composition of matter encompassed by compounds that alter expression level of polypeptides.

VII. Claims 42-47, in so far as they are drawn to a composition of matter encompassed by peptide mimetics.

VIII. Claim 48, drawn to a method for determining the activity or presence of a Preadipocyte-Factor-1-like polypeptide comprising contacting a cell with a ligand that binds the polypeptide of SEQ ID NO: 2.

IX. Claim 48, drawn to a method for determining the activity or presence of a Preadipocyte-Factor-1-like polypeptide comprising contacting a cell with a ligand that binds the polypeptide of SEQ ID NO: 4.

X. Claims 49-51, in so far as they are drawn to a method comprising genetically engineering cells with a vector or nucleic acid comprising SEQ ID NO: 1.

XI. Claims 49, 52 and 53, in so far as they are drawn to a method of treatment of a disease comprising administration of the polypeptide comprising the amino acid sequence of SEQ ID NO: 2.

XII. Claims 49, 52 and 53, in so far as they are drawn to a method of treatment of a disease comprising administration of the polypeptide comprising the amino acid sequence of SEQ ID NO: 4.

XIII. Claims 49, 52 and 53, in so far as they are drawn to a method of treatment of a disease comprising administration of the nucleic acid molecule SEQ ID NO: 1.

XIV. Claims 54-55, drawn to a method of screening candidate compounds effective to treat disease comprising protein interaction.

XV. Claim 56, drawn to a method for determining the activity or presence of a Preadipocyte-Factor-1-like polypeptide comprising contacting a cell with the nucleic acid molecule of SEQ ID NO: 1.

3. Inventions I-XV are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Furthermore, the products of Inventions I-XV do not reflect a single inventive concept because they do not share a common feature or combination of features that distinguishes them as a group from prior art.

The polypeptide of Groups I-II and polynucleotide of Group III are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide invention of Group III

does not necessarily encode the polypeptide of Group I. Furthermore, the information provided by the polynucleotide of Group III can be used to make a materially different polypeptide than that of Group I. In addition, while a polypeptide of Group II can be made the polynucleotide of Group III, it can also be recovered from a natural source using biochemical means, such as affinity chromatography, for example.

The ligands of Group V, the compounds of Group VI, and the peptide mimetics of Group VII are molecular structures that are materially distinct and subserve distinct physiological functions. Generally, ligands are proteins that mediate signal transduction processes within the cell and are structurally and functionally distinct from the pharmaceutical compounds of Group VI. Compounds could comprise of any number of bio-affecting natural organic molecules or synthetic organic polymer compositions. The compounds, as disclosed as modulating expression levels of polypeptides, which constitutes a distinct mode of use from that of the other products listed above. The inventions of ligands, compositions, and mimetics, as claimed, do not encompass overlapping subject matter, and there is nothing of record to show them to be obvious variants of each other.

The Inventions of Groups VIII through XV are each directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these methods would be used together. The methods of Groups VIII-XV are all unrelated as they comprise distinct steps and utilize materially different products, which demonstrates that each method has a

different mode of operation. Each invention performs this function using structurally and functionally divergent material and the specific methodology necessary for utilization of such materials would differ significantly for each method.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is

the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT. F 6 am to 3 pm, T & R 5:30 am - 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

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